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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,572	05/14/2004	Itzhak Bentwich	050992.0202.CPUS01	3571
37808 ROSETTA-GE	7590 04/11/200° ENOMICS		EXAMINER	
c/o PSWS		•	WOLLENBERGER, LOUIS V	
700 W. 47TH S SUITE 1000	STREET		ART UNIT	PAPER NUMBER
KANSAS CIT	Y, MO 64112		1635	
SHORTENED STATUTOR	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		04/11/2007	PAPER	

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

#### **DETAILED ACTION**

#### Election/Restrictions

Applicants' timely election with traverse of Group I, Claims 1–11 and 20-23, drawn to a bioinformatically detectable oligonucleotide, in the reply filed on January 30, 2007, is acknowledged. Also acknowledged is Applicant's election of a single sequence corresponding to said oligonucleotide, wherein Applicant has elected SEQ ID NO:10,068,308, and a single target gene, wherein Applicant has elected EGFR having sequence SEQ ID NO:783894. The latter election is moot in view of the cancellation of claims 1-11 and 20-23 and the presentation of new claims 25–38, which recite neither EGFR nor SEQ ID NO:783894.

With regard to the restriction to a single invention among Groups I–V, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of Group I has been treated as an election without traverse (MPEP § 818.03(a)).

With regard to the restriction to a single nucleotide sequence for prosecution with the elected invention, Group I, Applicant traverses the restriction citing the publication Examination of Patent Applications Containing Nucleotide Sequence, 1192 O.G. 68 (November 19, 1996) and MPEP 803.04, and arguing that the Examiner has failed to demonstrate that the claimed sequences are an exceptional case necessitating that the number of sequences to be selected be less than ten.

Applicants' reference to the U.S. Patent and Trademark Office policy regarding the examination of patent applications that claim large numbers of nucleotide sequences in the Official Gazette, 1192 O.G. 68 (November 19, 1996) is acknowledged, however, not found

persuasive on the basis that this policy regarding the partial waiving of the requirements of 37 CFR 1.141 is such that it will permit a reasonable number of nucleotide sequences to be claimed in a single application. Under the policy, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction. The waiver is permissive in nature and not a requirement. The waiver was written in 1996, well before the exponential growth of the nucleic acid databases.

Given that each sequence requires a separate search and consideration of the patent and non-patent literature, and given that a search of more than one (1) of the sequences claimed in the instant claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner, one (1) nucleotide sequence is considered to be a reasonable number of sequences for examination.

The requirement is still deemed proper and is therefore made FINAL.

## Status of the application

Claims 1–24 have been cancelled by Applicant in the reply filed 1/30/07. New Claims 25-38 are now pending. While new claims 25-38 recite the elected nucleotide sequence, SEQ ID NO:10,068,308, the claims also recite several other non-elected sequences such as SEQ ID NO:45, 159, 1166, 3201, 7870, 6769403, 6821380, 6825827, 6842315, and 6863394. Because the substitute CRF and paper copy listing of the sequences are flawed (see below), the Examiner is unable to review the sequence listing to determine whether the additional sequences read on,

or are subgeneric to, the elected invention. These additional sequences may be subject to restriction if the additional sequences are in fact each independent or distinct one from the other.

## CRF Sequence Listing—Notice to Comply

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

In the instant case, Applicants have submitted a substitute CRF copy of the sequence listing in the reply filed on 1/30/07; however, the Office's STIC Biotechnology Systems Branch is unable to process the substitute CRF for the reasons given on the attached Raw Sequence Listing Error Report. Thus, the Examiner is unable to search and examine the claims of the instant application.

Applicants are requested to resubmit the sequence listing in corrected form along with the necessary papers and statements.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louis V. Wollenberger, Ph.D. Examiner
Art Unit 1635
March 17, 2007

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# STIC Biotechnology Systems Branch

FW/6 **CRF** Problem Report

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) experienced a problem when processing the following computer readable form (CRF):

Application Serial Number: Filing Date: Date Processed by STIC:

STIC Contact: Mark Spencer: Telephone: 571-272-2510; Fax: 571-273-0221

#### **Nature of CRF Problem:**

	(circle one) Damaged or Unreadable (for Unreadable, see attached)
	Blank (no files on CRF) (see attached)
	Empty file (filename present, but no bytes in file) (see attached)
	Wrong file saved to CRF (invention title, docket number, or applicant(s) do not
	match those in official application) (see attached)
	Not saved in ASCII text
	Sequence Listing was embedded in the file. According to Sequence Rules,
	submitted file should only be the Sequence Listing.
	Did not contain a Sequence Listing. (see attached sample)
<u></u>	Other
In	lividual sequeron listed as files on the EFS submers

PLEASE USE THE CHECKER VERSION 4.4.0 PROGRAM TO REDUCE ERRORS. **SEE BELOW FOR ADDRESS:** 

http:/www.uspto.gov/web/offices/pac/checker/chkrnote.htm

- 1. EFS-Bio (<a href="http://www.uspto.gov/ebc/efs/downloads/documents.htm">http://www.uspto.gov/ebc/efs/downloads/documents.htm</a>, EFS Submission User Manual - ePAVE)
- 2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
- 3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05): U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/20/06

Sequents 56.txt L one of several files on submitted CD

(210> 8875302 L this is the first sequence
(211> 22
(212> DNA
(213> Homo sapiens

(400> 8875302
ctggctgggt tccaggattc ca

(210> 8875303
(211> 22
(212> DNA
(213> Homo sapiens

(400> 8875303
(211> 22
(212> DNA
(213> Homo sapiens
(400> 8875303
(211> 22
(212> DNA
(213> Homo sapiens
(400> 8875303
ctgctgggt tccaggattc ca

(400> 8875303
ctgctgggt tccaggattc ca
(400> 8875303
ctgctgggt tccaggattc ca
(400> 8875303
ctgctgggt tccaggattc ca
(400> 8875303
ctgctgggt tccaggattc ca

1) Per 1.824 of Sequence Rules: submit
only one file
for the Sequence
Listing